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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,914	01/05/2006	Margaret Han Dugan	ON/4-32695A	6406

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
TEALE, MICHAEL J	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,914	DUGAN ET AL.	
	Examiner	Art Unit	
	Michael J. Teale Ph.D.	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I claims 1-6 in the reply filed on 12/05/2007 is acknowledged. Election of the 4-pyridylmethyl-phthalazine derivative PTK787 is also acknowledged, and for the record applicant's election appears to read on claims 1-6. Claims 7-12 are withdrawn along with methods of use and compositions comprising compounds other than PTK787, from further consideration as drawn to nonelected inventions, there being no allowable generic or linking claim.

Applicant is advised that the restriction is made **Final**.

The Information Disclosure Statement (IDS) filed March 3, 2005 is acknowledged. Applicant is advised that none of the references listed in the IDS were included in the filing.

2. ***Claim Rejection - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating myelodysplastic syndromes in a warm-blooded animal or human by administering PTK787. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988). These factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

Factors 1 and 2) The claimed invention is directed to a method for treating myelodysplastic syndromes (MDS) in a warm-blooded animal or human by administering PTK787 (claims 1-6).

Factor 5) The instant specification examples (pages 9 and 10 of the specification as filed) disclose twelve patients having untreated advanced MDS. It is reported administration of PTK787 gave two of the patients some relief from their symptoms. This result seems to reflect a diversity of underlying causes and supports the notion that one drug is not effective against a class of diseases like MDS. While this result may be enabling for treating some form of MDS, the specification does not reveal what form(s) of MDS the patients suffered from. Furthermore, the results suggest that ten of the patients have a form of the disease that is not treated by PTK787.

Factor 7) MDS refers to a diverse group of hematopoietic stem cell disorders characterized by a cellular marrow with impaired morphology and maturation (dysmyelopoiesis),

peripheral blood cytopenias, and a variable risk of progression to acute leukemia, resulting from ineffective blood cell production (Greenberg, The Myelodysplastic Syndromes, 2000).

Summary

As the cited art and discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that PTK787 would be effective in treating all forms of MDS. It is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. §112, first paragraph. Given that the applicant has failed to demonstrate that warm-blooded animals and/or humans with any form of MDS could be treated by the administration of PTK787, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claims 1-6 are rejected.

Claim Rejection - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton *et al.*, (US 2003/0096875).

The instant application claims are drawn to a method for treating myelodysplastic syndromes (MDS) in a warm-blooded animal and/or a human via daily administering PTK787 (claims 1-6).

Burton teaches the treatment of MDS (page 1, paragraph [0010] and claim 4) with anticancer agents that include PTK787 (page 1 & 2, paragraph [0013] and claim 21). Furthermore, Burton teaches the use of an "effective amount" of the invention (page 3, paragraph [0027]) and that an attending physician will decide the dosage regimen for the patient (paragraphs [0027], [0138] and [0139]). The medicament is to be delivered in unit dosage form (page 4, paragraph [0167]).

Since Burton teaches that cancers (including MDS) may be treated with the inventive compound PTK787, using effective amounts in dosage regiments to be determined by the attending physician delivered in unit dosage form, it would have been obvious for some one of ordinary skill in the art to use the compound to treat MDS that is resistant to conventional chemotherapy. A physician of ordinary skill in the art would have been motivated to use the compound as suggested by Burton because PTK787 is not a conventional cancer chemotherapeutic agent.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Teale Ph.D. whose telephone number is (571)-272-6897. The examiner can normally be reached on 7:30 am to 4:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJT

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER

1/18/08